AMENDMENTS TO THE DRAWINGS

Please substitute the attached replacement sheets of drawings for Figures 1, 3 and 4 for the original sheets of drawings for Figures 1, 3 and 4. The replacement drawings have been presented to show the inner and outer surfaces of the sample collection part.

Attachments: Replacement sheets of Figures 1, 3 and 4, as amended.
Annotated sheet of Figures 1, 3 and 4 showing the changes.

REMARKS

This is a full and timely response to the Office Action mailed July 22, 2009, submitted concurrently with a one month extension of time to extend the due date for response to November 23, 2009.

By this Amendment, the specification and drawings have been amended to address the objections to the drawings. Further, claims 1, 5, 6 and 11 has been amended to address the objections to the drawings and claims, and to more particularly define the present invention. Thus, claims 1-11 are currently pending in this application. Support for the amendments to the specification, claims and drawings can be readily found variously throughout the specification and the original claims, see, in particular, paragraphs [0046] and [0080] of the present Patent Application Publication No. US 2006/0199275 A1.

In view of these amendments, Applicant believes that all pending claims are in condition for allowance. Reexamination and reconsideration in light of the above amendments and the following remarks is respectfully requested.

Objection to the Drawings

The drawings are objected to for the minor informalities set forth in item 1 of the Action. In particular, the Examiner asserts that the inner and outer surfaces of the sample collection part, and the flow channel opposite the through hole must be shown in the Figures. Applicant respectfully traverses this objection.

Applicant believes that the Figures clearly show the sample collection part 3. Applicant also believes that it is easy to discern the inner and outer surfaces of the sample collection part 3 therefrom (see the inner and outer surfaces of the sample collection part 3 shown in at least in Figures 1, 3, and 4). Further, Applicant notes that there is no requirement that every feature of the claims be designated by a reference numeral.

Nevertheless, in the interest of expediting the prosecution of the present application, Applicant has amended Figures 1, 3 and 4 to show the inner and outer surfaces of the sample collection part and effect corresponding amendments to the specification. Further, Applicant has amended claim 11 to more particularly define that the flow channel (*opposite the through hole*)

comprises a recess formed in a part of an outer periphery of the press-in portion of the plug member which is shown in the Figures. Applicant notes that the feature of the flow channel is shown, for example, in Figure 10 of the present Patent Application Publication, wherein the plug member 64 can be slightly drawn out upward such that the through hole 62b is opposite to the recess 64d (flow channel) (see paragraph [0081] of the present Patent Application Publication).

Thus, in view of the amendments to the specification, drawings and claims, this objection can no longer be sustained and should be withdrawn.

Objection to the Claims

Claims 5 and 6 are objected to for the minor informalities set forth in item 2 of the Action. Specifically, the Examiner argues that claims 5 and 6 are directed to a method, but are dependent on claim 4, which is directed to an apparatus (see page 3 of the Office Action). Applicant has overcome this objection by amending the preamble of claims 5 and 6 to "*~~The method of filtering a sample jig~~ according to claim. . ..*" Thus, withdraw of this objection is respectfully requested.

Rejections under 35 U.S.C. §102 and §103

Claims 1, 2 and 7-11 are rejected under 35 U.S.C. §102(a) as allegedly being anticipated by Stevens et al. (U.S. Patent Application Publication No. 2004/0013575). Further, claim 3 is rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Stevens et al. (U.S. Patent Application Publication No. 2004/0013575) in view of Brown et al. (U.S. Patent No. 3,837,376). Further, claims 4-6 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Brown et al. (U.S. Patent No. 3,837,376) in view of Altman et al. (U.S. Patent Application Publication No. 2002/0177772). Applicant respectfully traverses these rejections.

To constitute anticipation of the claimed invention under U.S. practice, the prior art reference must literally or inherently teach each and every limitation of the claims. Further, to establish an obviousness rejection under 35 U.S.C. §103(a), four factual inquiries must be examined. The four factual inquiries include (a) determining the scope and contents of the prior art; (b) ascertaining the differences between the prior art and the claims in issue; (c) resolving the level

of ordinary skill in the pertinent art; and (d) evaluating evidence of secondary consideration. *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966). In view of these four factors, the analysis supporting a rejection under 35 U.S.C. 103(a) should be made explicit, and should "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed. *KSR Int'l. Co. v. Telefex, Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385, 1396 (2007). Further, the Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). Finally, even if the prior art may be combined, there must be a reasonable expectation of success, and the reference or references, when combined, must disclose or suggest all of the claim limitations. *See in re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Given Applicant's review of Stevens et al., Brown et al., and Altman et al., Applicant submits that the cited references, either alone or in combination, fails to teach or suggest all the limitations of the claims.

As noted in Applicant's previous response, the present invention is directed to (1) methods for filtering a sample using a sample collecting container, (2) a jig and (3) a sample collecting container. The sample collecting container is capable of not only securely completing filtration of a sample through a filter member using a reduced pressure in the container, but also eliminating an operation that may cause infection such as removing a plug member so as to complete the filtration. The sample collecting container includes a sample collection part, a filter member and a sample storage part.

Please note that the filter member is provided in the sample collection part, for filtering the sample collected in the sample collection part. The filter member is formed of an appropriate filter material for removing solid substances in the sample (see paragraph [0038] of the present Patent Application Publication). The filtration stops when the pressures of the upside space and the downside space of the filter member reach equilibrium in the sample collecting container. A jig is used to establish communication between the interior space of the sample collection part and the atmosphere, whereby a pressure difference is given between the internal space of the sample

collection part and the internal space of the sample storage part. Consequently, this pressure difference allows for progression of the filtration again.

Stevens et al. discloses a method and device for collecting and stabilizing a biological sample. More specifically, Stevens et al. discloses sample collection containers having a stabilizing additive contained therein for stabilizing proteases immediately on collection of a biological sample and for inhibiting protein degradation and/or fragmentation during storage thereof (see paragraph [0002] of Stevens et al.).

Stevens et al. further discloses a blood collection device 10 that includes a container 12 defining an internal chamber 14. The container 12 is a hollow tube having a side wall 16, a closed bottom end 18 and an open top end 20. The container chamber 14 includes a separating member 13 that assists in separating components of the sample. The open end 20 of the container can be covered by closure means 22, which may be a rubber closure, a HEMOGUARD® closure, a metallic seal, a metal-banded rubber seal, or a seal of different polymers and designs (see paragraph [0052] and Figure 1 of Stevens et al.).

The Examiner appears to rely on the portion of the container 12 above the separating member 13 to teach the claimed sample collection part, the closure means 22 to teach the claimed plug member, the separating member 13 to teach the filter member, and the portion of the container 12 below the separating member 13 to teach the claimed sample storage part (see page 3 of the Office Action). Thus, the Examiner argues that the claims are anticipated by the structures disclosed and shown in Figure 1 of Stevens et al.

However, in contrast to the present invention, Stevens et al. fails to expressly disclose "*wherein after collecting a sample in the sample collection part using a vacuum blood collection needle, the sample is filtered by a pressure difference between the sample collection part and the sample storage part, while the plug member is pierced by a communication needle having a communication flow channel to establish communication between the sample collection part and the exterior, thereby elevating the internal pressure of the sample collection part.*" In addressing this limitation, the Examiner asserts that this feature is inherent in Stevens et al. (see page 3 of the Office Action). However, Applicant disagrees with the Examiner's position.

"To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill in the art." *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d, 1949, 1950-51 (Fed. Cir. 1999) (citations omitted). "In relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 UiSPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). "The fact that a certain result or characteristic *may occur or be present* in the prior art is not sufficient to establish the inherency of that result or characteristic." MPEP § 2112.IV (citing to In re Rijckaert, 9 F.3d 1531, 1534, (Fed. Cir. 1993)) (emphasis added).

Stevens et al. discloses that the pressure in chamber 14 is selected to draw a predetermined volume of biological sample into the chamber 14. Hence, the closure 22 maintains the internal pressure differential between atmospheric pressure and a pressure less than atmospheric. Further, the closure 22 is pierced by a needle 26 to introduce a biological sample into the container 12, after which the closure is resealed (see paragraph [0054] of Stevens et al.). Thus, the needle 26 is used only to deposit the sample into the chamber 14 and not used to establish communication between the interior space of the chamber 14 and atmosphere since *after* the sample is deposited, the closure is resealed. As such, the needle 26 corresponds only to the vacuum blood collection needle of the present invention.

It should also be noted that when the closure 22 is pierced by the needle 26 in Stevens et al., the outer end of the needle is connected to the source of the biological sample and not open to the atmosphere. Thus, it is not possible for Stevens et al. to inherently teach or suggest that "*the plug member is pierced by a communication needle having a communication flow channel to establish communication between the sample collection part and the exterior, thereby elevating the internal pressure of the sample collection part.*"

Further, the present invention recited in claim 1 is directed to a method and not to a product. In other words, claim 1 clearly defines a step of collecting the sample into the sample collection part of the container by the vacuum blood collection needle and a step of establishing communication between the sample collection part and the atmosphere by the communicating

needle after collecting the sample. Such method steps cannot be found to be inherently disclosed by Steven et al. merely by the structures shown in Figure 1 of Steven et al. The Examiner must point out how Steven et al. inherently teaches the use of such structures to practice the method steps of the present invention. For the reasons noted above, such teachings can not be found in Steven et al.

Furthermore, Stevens et al. fails to make any disclosure regarding filtering by means of a pressure difference between the sample collection part and the sample storage part or that the filtering stops when the pressure difference is reduced. Rather, Stevens et al. only discloses that "*the separating member 13 serves to assist in separating components of the sample, for example, by centrifugation*" (see paragraph [0052] of Stevens et al.).

Therefore, Applicant believes that the teachings of Stevens et al. does not make clear that the missing descriptive matter (i.e. the methodology of "*wherein after collecting a sample in the sample collection part using a vacuum blood collection needle, the sample is filtered by a pressure difference between the sample collection part and the sample storage part, while the plug member is pierced by a communication needle having a communication flow channel to establish communication between the sample collection part and the exterior, thereby elevating the internal pressure of the sample collection part*") is necessarily present in the disclosure of Stevens et al.

Nevertheless, to further emphasize these distinctions between the present invention and Stevens et al., Applicant has amended claim 1 to recite "*wherein a communication between an internal space of the sample collection part and atmosphere occurs (1) after collecting the sample in the sample collection part and (2) due to the piercing of the plug member by the communication needle having the communication flow channel.*"

With regard to claims 7, 10 and 11, Stevens et al. fails to disclose "*the sample collection part, the filter member and the sample storage part being hermetically connected with each other and the internal pressure of sample storage part being reduced in advance.*" The Examiner fails to address the feature of the internal pressure of the sample storage part in the Office Action, and Stevens et al. makes no disclosure with regard to reducing the internal pressure of the sample storage part. Thus, Applicant submits that the rejection of these claims cannot be sustained in view of the deficiency in the teachings of Steven et al. and the Examiner's arguments.

It appears that the Examiner is not giving the internal pressure feature of the present invention any patentable weight since internal pressure does not define structure. However, Applicant believes that the Examiner's reasoning is flawed since internal pressure is a physical property which has an effect on its environment (i.e. force per unit area that one region of a gas, liquid, or solid exerts on another). Thus, Applicant believes that the Examiner must address the failure of Steven et al. to teach the limitation "*the internal pressure of sample storage part being reduced in advance*."

In addition, Applicant also believes that the closure and the piercing and resealing of the closure disclosed in Steven et al. are not equivalent in structure to the claimed elements of the through hole, removable sealing member, and flow channel of claims 7-11. Paragraph [0054] of Steven et al. only teaches that the closure can be pierced by a needle or other cannula to introduce a biological sample. Such teachings in Steven et al. only arguably corresponds to the vacuum blood collection needle of the present invention but do not define additional structural elements which corresponds to the through hole, removable sealing member, and flow channel of claims 7-11. It is clear from the specification and drawings of the present application that such structural elements are not present in the blood collection device of Stevens et al.

For example, with regard to claims 10 and 11, and the limitations recited therein (i.e. "*wherein . . . a flow channel is formed in a part of outer surface of the plug member contacting the inner surface of the sample collection part, the flow channel establishing communication between the through hole and the interior of the sample collection part when its circumferential position is brought into coincidence with the through hole*," and "*wherein . . . a flow channel is formed in the plug member in such a manner that when the plug member is drawn out from the sample collection part while keeping hermetical sealing between the plug member and the inner surface of the sample collection part, one end of the flow channel is opposite to the through hole and the other end of the flow channel is open in the sample collection part*"), Stevens et al. does not teach or suggest any structural elements which correspond to the flow channel and through hole for establishing communication between the through hole and the interior of the sample collection part when the flow channel's circumferential position is brought into coincidence with the through hole, or when the plug member is partially drawn out from the sample collection part such that one end of the flow

channel is opposite to the through hole and the other end of the flow channel is open in the sample collection part

It appears that the Examiner is interpreting the closure pierced by a needle in Stevens et al as being equivalent to a through hole and flow channel. However, such an interpretation does not address how such communication between the through hole and the interior of the sample collection part can be adjusted or manipulated based on the movements of the plug member. In addition, Stevens et al. clearly does not disclose establishing communication between the interior space of the chamber 14 and the atmosphere by any means such as the communicating needle, through hole and flow channel. As previously noted, the needle 26 in Stevens et al. is used only to deposit the sample into the chamber 14 (by piercing the closure 22 with the needle 26) and not used to establish communication between the interior space of the chamber 14 and atmosphere since *after* the sample is deposited, the closure is resealed by the removal of the needle 26 (see paragraph [0054] of Stevens et al.)

Thus, Applicant believes that the Examiner's interpretation of Stevens et al. still does not read on claims 10 and 11 as presently presented.

Nevertheless, Applicant notes that in response to the objection to the drawings, claim 10 has been amended to recite:

> "*wherein the plug member comprises a gripping portion and a press-in portion, and*
> *wherein the flow channel comprises a recess formed in a part of an outer periphery of the press-in portion.*"

Applicant believes that such an amendment clarifies the location of the through hole and flow channel and that the through hole and recess of the plug member form a open flow channel when the plug member is rotated or drawn out from the sample collection part (*while maintaining the hermetic seal between the plug member and the inner surface of the sample collection part*) Such structural features of the through hole and flow channel are clearly distinguishable from the Examiner's interpretation of Stevens et al.

Brown et al. discloses a serum collection tube that comprises a hollow cylinder whose ends are closed off by novel "one shot" valve structures, and whose lower end also carries a piston member. The valves comprise self-sealing elastomeric end caps pierced by portions of an elongated

one-piece removable hollow needle (see column 1, lines 56-62, of Brown et al.). Specifically, Brown et al. discloses an elongated hollow needle 20 which is used to pierce the upper sealing element 18 of a flange 16. The needle 20 is provided with openings or ports 5, 6 separated by a seal 7 formed by crimping or the like. The port 5 and the upper needle opening 3 provide communication between the inside of the tube 15 and the atmosphere. The needle 20 mounts a head or grippable portion 21, which is adapted to be grasped by a user to facilitate the subsequent removal of the needles 20 from the upper sealing element 18 and a lower sealing element 22 after serum collection (see column 2, lines 53-67, of Brown et al.).

In contrast to the present invention, Brown et al. does not disclose *a skirt portion extending in the axial direction of the communication needle from the gripping portion.* The Examiner cites element 15 of Brown et al. to teach this element (see page 7 of the Office Action). However, element 15 of Brown et al. is the collection tube, and not a skirt, and it does not extend from the grippable portion 21. Thus, Applicant believes that Brown et al. fails to teach or suggest this feature of the present invention.

Further, Brown et al. also fails to disclose "*at least one vane provided on the side of the needlepoint of the communication needle, wherein the vane has a shape that approaches the communication needle as they extend to their tip ends.*" The Examiner cites Altman et al. to cure this deficiency in Brown et al.

Altman et al. discloses structures and catheter systems to achieve site specific delivery of therapeutic agents, and means for implanting and using these systems to enable delivery of therapeutic agents to the body (see paragraph [0002] of Altman et al.). Specifically, Altman et al. discloses a fixation mechanism consisting of a needle 484 with apertures 486 that penetrates the myocardium and is held in place by barbs 466 (see paragraph [0083] and Figure 4 of Altman et al.). Thus, it is clear that the function of the needle and barbs 466 in Altman et al. is very different from the communication needle and vane of the present invention.

The Examiner proposes adding the barbs of Altman et al. to the needle 20 of Brown et al. to form a vane at the needlepoint in order to prevent random movement of the needle (see page 8 of the Office Action). However, Applicant does not believe that one of ordinary skill in the art would have been motivated to modify Brown et al. in view of Altman et al. Brown et al. is directed to a

serum *collection* tube, whereas Altman et al. is directed to a *delivery* system. Thus, the inventions of Brown et al. and Altman et al. serve very different purposes.

The needle 20 in Brown et al. is merely used to collect serum (which is already separated from blood by centrifugation) into a serum collection tube. Further, as already argued in the prior response, the apparatus shown in Brown et al. aims to remove blood serum from the centrifuged specimen tube by securely trapping the blood serum within the collection tube (see column 3, lines 31-34, of Brown et al.). Even before the apparatus is utilized, blood samples are centrifuged in accordance with well known procedures (see column 2, lines 31-34, of Brown et al.). Therefore, Brown et al. does not have or need a filter member for its apparatus to work. Accordingly, since the pressure difference for filtration is not required in Brown et al., there is no need to establish communication between the interior space and the atmosphere in Brown et al.

The Examiner argues that the inner and outer space of the tube 15 are communicated by the port 5 and upper aperture 3. However, the port 5 in Brown et al. is provided to remove or introduce air so that the serum is introduced into the tube or the excess amount of serum is discharged. Hence, Applicant believes that Brown et al. does not teach communication between the interior space of the collection tube and the atmosphere as required by the present invention.

Further, Brown et al. relates to an elongated one-piece *removable* hollow needle (see column 1, lines 59-62, of Brown et al.). The needle 20 in Brown et al. is required to be removable from the tube 15. The addition of the barbs 466 in Altman et al. to the needle 20 in Brown et al. would interfere with and prevent the removability of the needle 20. Thus, Applicant believes that one of ordinary skilled in the art would not be motivated to modify the needle in Brown et al. with the barbs in Altman et al. since such modification would make the needle in Brown et al. unsatisfactory for its intended purpose (i.e. removal of the needle 20 from the tube 15) and greatly decrease the intended utility of the apparatus of Brown et al. Under U.S. case law, if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Thus, for these reasons, withdrawal of the present rejections is respectfully requested.

CONCLUSION

For the foregoing reasons, all the claims now pending in the present application are believed to be clearly patentable over the outstanding rejections. Accordingly, favorable reconsideration of the claims in light of the above remarks is courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the below-listed number.

Dated: November 23, 2009

Respectfully submitted,

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